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The Food Safety People

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VIA EMAIL

Dockets Management Branch
Mail Code HFA-305
Food and Drug Administration
Rm 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Docket No. 02N-0278; Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Comments on Section 307, Prior Notice of Imported Food Shipments

RE: Docket No. 02N-0275; Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Comments on Section 303, Administrative Detention

Dear Sir or Madam:

The National Food Processors Association (NFPA) appreciates the opportunity to submit comments in anticipation of a proposed rulemaking on the above referenced sections of The Public Health Security and Bioterrorism Preparedness and Response Act (Act), as applicable to the statutory provisions for prior notice of imported food shipments and administrative detention. NFPA recognizes that, under the Act, the Secretary is required to issue final regulations addressing Section 307 by December 12, 2003. NFPA is providing these comments to assist FDA in meeting that statutory deadline.

NFPA is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers. NFPA members import ingredients for further processing and would be affected by the rulemaking that has been mandated under the Act.

02N-0278

EC 17

General Comments

In order for the prior notice provision of the Act to achieve its purpose, be workable, and result in the minimal disruption of food importation, processing, and distribution in the United States, NFPA believes that numerous factors must be considered and reflected in the final regulation. These factors include consistency and seamless integration with existing and pending import notification requirements (most notably those of the U.S. Customs Service, Department of the Treasury), with the goal of minimizing or eliminating unnecessary, multiple or redundant notification. Changes in FDA operating procedures should be considered to ensure 24 hours per day, 7 days per week (24/7) coverage of import operations. Conditions of international agreements must be satisfied to avoid potential trade disputes or retaliation. Key operational issues must also be carefully considered, including: the responsible party for prior notice; the appropriate time frame; transmission of the information to FDA; and, receipt and "appropriate" FDA response.

NFPA urges FDA to consider the remarks of Congressman John Shimkus (IL), a sponsor of H.R. 3448 on its introduction in the House of Representatives on December 11, 2001, who noted that trade must not be disrupted unnecessarily by the prior notification requirement, or by the time and process of FDA's determination that requirements have been met. Also, as stated in the statute, FDA should note that the prior notice does not prescribe the final port of entry for a specific shipment of imported food. This qualification will require FDA to have a system with sufficient flexibility and dissemination of information to allow for and accommodate unforeseen changes in the final port of entry.

In developing the prior notice requirements, NFPA encourages FDA to recognize that the objective of the statutory provision is to provide the Agency with information to facilitate the release of a shipment into commerce within the United States. The general purpose throughout the Act is to determine if credible evidence exists that the food presents a threat of serious adverse health consequences or death to humans or animals.

Use Existing Mechanisms To Provide Notice

The food industry agrees that prior notification requirements should be integrated into existing US Customs Service systems, and that there is no need to create a new or different system and procedures in order to satisfy the statutory requirements. Customs currently operates through the Automated Broker Interface (ABI), a component of the Customs Service Automated Commercial System (ACS) that allows participants voluntarily to file electronically required import data. Currently 96 percent of all entries are filed through ABI. The ACS interfaces with other government agencies (including FDA through OASIS) to electronically transfer data on import transactions. The Border Release Advanced Screening and Selectivity System (BRASS) then scans the information, verifies the data, establishes an entry, releases the cargo and provides ABI

participants release information. Currently all of the information required by the Act, except information pertaining to grower, is provided through the ABI.

Enhancements to the OASIS system and modifications to ABI will be necessary to resolve existing inconsistencies in information and operational procedures to satisfy the provisions of the Act. As noted in the FDA stakeholders meeting of July 30, 2002, the prior notice regulations involve significant information technology components, and the existing FDA OASIS system must be adequately enhanced to accommodate these electronic submissions. The system must accommodate FDA's statutory deadlines and time frame, yet provide flexibility to allow additional information that may be required by Customs to be provided at entry, as is the current practice (quantities, for example, in order to determine tariff or quota information).

Appropriate linkages between the Customs information and FDA prior notice information must be addressed. Customs entry numbers are often not assigned until the product enters port. Finally, NFPA points out that four percent (4%) of entries currently do not use the ABI electronic system and those entries must be taken into consideration.

Information Presentation

NFPA believes that the information required by the Act (the article, the manufacturer and shipper, the grower if known, the country of origination and shipping, and the anticipated port of entry) would be sufficient to satisfy the intended objectives of the statute, is generally consistent with current Customs practice and is not unduly burdensome. Some NFPA member companies believe that "voluntary" screens may be appropriate to display information pertaining to "low-risk" status or other data to help expedite clearance on entry.

NFPA also notes that the statute refers to "article of food" but does not define "article." NFPA encourages FDA to clarify that "article" is intended to apply to the finished food product as described on the shipping documentation and not to specific ingredients contained in the food. An alternative interpretation would have significant implications by creating an unintended burdensome process to identify country of origin, manufacturer and related information for ingredients. This would be inconsistent with U.S. trade commitments and obligations in that it would be more trade restrictive than necessary to achieve a legitimate security objective. Likewise, FDA's interpretation of "country of origin" should be consistent with existing Customs regulations and is already captured in the ACS and OASIS systems.

NFPA notes that the statutory language requires providing information on the "grower," if known within the predetermined time frame. The grower will not be known for a significant amount of imported shipments, since many bulk commodities are commingled from several suppliers and combined. Ingredients for use in processing also may be commingled or combined, or they could be partially processed. They may not be shipped directly from initial production, but may be processed and packaged in the exporting

nation. In such a case, the grower could not be known without a burdensome and unnecessary trace back system.

Consequently, NFPA recommends that "unknown" on the notification should suffice and should not trigger a new obligation to inquire for additional information by either FDA or the importer while trade is disrupted. FDA should recognize that for certain product categories it is unreasonable and unnecessary to provide grower information, and FDA should assume that a good faith effort will be made to supply that information when available. FDA must also realize that responsibility for the safety and security of the product lies with the party that last handled the product, particularly in the case of a substantial transformation, and that the identity of the grower becomes increasingly irrelevant the more the food product is processed.

Responsible Party Should Be Clarified

The Act does not identify the party who should be responsible for providing the notice nor the format in which the information is to be provided. While NFPA believes that some flexibility should be provided to accommodate current operational practices, particularly in format, it is necessary to spell out in regulations who is the responsible party. Custom's Trade Partnership Against Terrorism (CTPAT) relies on the "importer of record." "Importer" is also defined in Customs regulations in a manner that provides for appropriate flexibility (19 CFR 101.1). The ABI information is also consistent with this approach. Consequently, NFPA recommends FDA regulations include the same flexibility in identifying the responsible party.

NFPA believes the statute intends FDA acknowledgment of prior notice to be immediate and electronic (when notice is provided electronically), allowing only sufficient time for receipt and review. In order to accommodate acknowledgment of prior notice under the pre-determined time frame, it will be necessary for FDA to increase hours of operations at ports of entry to 24 hours per day, 7 days per week, consistent with those of U.S. Customs.

Notification Period Should Be Based Upon Mode Of Transport

The law specifies a maximum period of five days and a default period of no less than 8 hours and no more than five days. Customs does not currently establish a minimum time period for entry notification. Information is often not provided to Customs until the goods are ready to enter the port, and can be provided after the goods have arrived. Customs has proposed to amend 19 CFR Parts 4 and 113 to require advance manifest information prior to loading at foreign ports to facilitate release of cargo in the U.S. (67 FR 51519, August 8, 2002). The proposed rule is not entirely consistent with FDA's prior notice requirements because of statutory timing and information needs, but should also be considered in this rulemaking and within the FDA dialogue with Customs.

NFPA recommends that the maximum statutory time frame of five days remain in place. This time period is short enough to maintain the linkage between entry and shipment without overburdening port officials with outstanding shipments and related information. Customs rules currently allow an import entry (non-quota) to be submitted five days before the shipment arrives. NFPA has taken into consideration current distribution practices of the food processing industry and notes that many food processors are sourcing and producing perishable commodities. A one-size fits all approach in establishing a time period for prior notice may not be workable for all shipments but NFPA recommends that the notification variables should be limited to keep the system as simple as possible. NFPA believes the variable time frames should be based on mode of transport, with some consideration given to low-risk importers.

NFPA notes that 30 percent of all U.S. agricultural imports arrive from Canada and Mexico, most by land transport (truck and train). Many of those shipments are repetitive and often, time between loading and distribution within the U.S. is only hours. NFPA is particularly concerned about trade disruption to those cargos that excessive notification requirements may cause.

NFPA suggests the following:

- For cargo arriving by plane, notification requirement should be "wheels up" (time of departure) regardless of point of origin. This would be consistent with current Customs operational practices.
- For land cargo (train or truck), notification requirements should be as short as possible to accommodate the requirements of the Act. NFPA suggests that FDA establish a minimum prior notice of two hours or less prior to entry for land cargo.
- Providing prior notice for ocean cargo is less of a problem. NFPA companies believe they could accommodate the statutory default of eight hours. However, especially for cargo by ship, defining the "time of importation" is important. FDA should specify whether this means time of docking, arriving in port, or entry into U.S. waters. Customs defines "date of importation" as the date "on which the vessel arrives within the limits of a port in the U.S. with intent then and there to unlade such merchandise" (19 CFR 101.1). Customs' definition does not sufficiently satisfy the need created through regulations promulgated under the Act.

Finally, NFPA believes that it is appropriate to recognize "low risk" importers by expediting notification, review and response or "may proceed" instructions for "low-risk importers." Customs' already has a system in place to sort high risk cargo from low risk cargo (cargo selectivity system) and the ACS Entry Summary Selectivity System matches criteria against entry data to assess risk by importer, tariff numbers, country of origin, manufacturer, and value. In addition, Customs has recently created CTPAT to provide for facilitating trade by participating importers who have appropriate security systems in place. Many food companies have applied for CTPAT. Linking the programs would

encourage participation in CTPAT and assist in achieving the ultimate statutory goal of improved security.

Flexibility Must Be Provided To Accommodate Changes

As previously noted, unforeseen circumstances including inclement weather, shipping delays, or unanticipated operational needs may require a change in the port of entry or timing. It also is possible that new information will surface between notification and entry that could require an amendment to the filed notice. NFPA points out that the new information is likely to relate to Customs requirements (such as quota information) or to FDA requirements. For example, grower information may become known during transit. Consequently, NFPA urges FDA to work with Customs to provide for some flexibility to accommodate those circumstances without undue delay. A change should not necessarily result in detention or in re-notification that would initiate a new minimum time period. Clearly the need for flexibility will depend, to some degree, on the established minimum time frames for notification.

FDA must also consider how to accommodate "less than load" (LTL) shipments. An LTL shipment could occur where one manufacturer fills a truck with an additional product (that had not been identified on the prior notification) or where a trailer may be filled with products from several locations before entering the US. Likewise one truck may contain orders from several companies (importers) intending delivery to several sites within the US. Consequently, depending upon assignment of responsibility for providing notice, a single cargo could be used to accommodate several notices arriving at FDA at different times. In addition, a concern arises where it may take several days (more than the 5 days maximum) to load the truck in various sites prior to delivery within the U.S.

Failure To Comply

The Act requires that food offered for import where prior notice has not been provided shall be held at port of entry until the importer complies, and directs the Secretary to determine whether there is any credible evidence indicating a serious adverse health consequence. The Act does not provide for other penalties. NFPA urges FDA to maintain a clear separation between "holding" a product or shipment for failure to provide prior notice and administrative detention under Section 303. Unless a serious adverse health consequence has been identified, the product should only be held until prior notice requirements have been met and FDA has an opportunity to review and respond.

Administrative Detention

Section 303 of the Act authorizes FDA to order the detention of food on credible evidence that it presents serious adverse health consequences and states that such decision is to be made at district director level or higher and mandates some specific

rulemakings. The law establishes no mandatory time frame for this provision although FDA has indicated an intent to proceed concurrently with the statutory deadlines for other provisions.

NFPA notes that the law allows the detention order to require marking and removal to a secure facility. Section 308 authorizes the Secretary to require marking of refused food at the expense of the importer. NFPA also notes that on August 21, 2002, proposed regulations on marking for refused imports (67 FR 54138) were withdrawn by FDA because of inconsistencies with the Act. The industry has grave concerns that the manner of marking may have significant implications on future ability to distribute or market the product resulting in severe adverse economic consequences. FDA should recognize that in some cases, initial evidence may indicate the imported product presents a serious health threat, but upon inspection it may be determined to be a safe product and be released into commerce. In such a case, the marking should not require significant reconditioning for distribution.

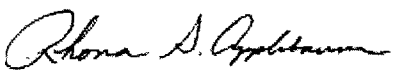
NFPA also notes, and fully supports, statutory requirements for expedited procedures for perishable foods and transfer to secure storage.

Summary

In conclusion, NFPA urges FDA to recognize that the intent of the prior notice provision is to obtain information that will facilitate safe release of the product into the channels of trade. The statutory requirements can be accommodated without undue burden to the food industry or regulators by using the existing Customs electronic system, recognizing that enhancements to technology will be needed as well as agreements between the agencies on procedures and information management. NFPA stresses the importance of increasing FDA hours of operation at entering ports to 24/7 in order to ensure successful implementation of the prior notice requirements without disruption to trade.

NFPA thanks you for consideration of these comments, anticipates an opportunity to respond to FDA's regulatory proposals and welcomes the challenge of working with FDA towards a safer and more secure food supply.

Regards,



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